

INFORMATIONAL LETTER NO. 2042-MC-FFS

DATE: August 29, 2019

TO: Iowa Medicaid Physicians, Dentists, Advanced Registered Nurse

Practitioners, Therapeutically Certified Optometrists, Podiatrists, Pharmacies, Home Health Agencies, Rural Health Clinics, Clinics, Skilled Nursing Facilities, Intermediate Care Facilities, Nursing Facilities-Mental ILL, Federally Qualified Health Centers (FQHC), Indian Health Service, Maternal Health Centers, Certified Nurse Midwife, Community Mental Health, Family Planning, Residential

Care Facilities, ICF/ID State and Community Based ICF/ID

Providers, and Physician Assistants

APPLIES TO: Managed Care (MC), Fee-for-Service (FFS),

FROM: Iowa Department of Human Services (DHS), Iowa Medicaid Enterprise (IME)

RE: Iowa Medicaid Pharmacy Program Changes

EFFECTIVE: October 1, 2019

1. Changes to the Preferred Drug List (PDL) Effective October 1, 2019. Refer to the PDL website¹ to review the complete PDL.

<u>Preferred</u>	Non-Preferred	Non-Recommended
Cutaquig	Albuterol HFA	Balversa*
Cuvitru	Aliskiren	Herceptin Hylecta*
Hizentra	Ambrisentan*	Vitrakvi*
Inbrija	Arikayce	
Ranolazine	Bosentan*	
Rocklatan	Buprenorphine/	
	Naloxone Film*	
Tarceva*	Deferasirox*	
Tresiba Vial	Diclofenac Epolamine*	
	Dovato	
	Duobrii*	
	Erlotinib*	
	Firdapse	
	Insulin Lispro Pen*	

¹ http://www.iowamedicaidpdl.com/

Insulin Lispro Vial	
Inveltys	
Loteprednol	
Mavenclad*	
Mayzent*	
Mesalamine DR Cap	
Motegrity*	
Osphena*	
Penicillamine	
Qmiiz ODT*	
Skyrizi [*]	
Solifenacin	
Sympazan*	
Trepostinil*	
 Udenyca*	
Valchlor	
 Vyndaqel	

^{*}Clinical PA Criteria Apply

2. New Drug Prior Authorization Criteria- See complete PA criteria under the <u>Prior Authorization Criteria tab</u>².

Cannabidiol (Epidiolex):

Prior authorization is required for cannabidiol (Epidiolex). Payment will be considered under the following conditions:

- 1. Patient meets the FDA approved age; and
- 2. Baseline serum transaminases (ALT and AST) and total bilirubin levels have been obtained prior to initiating therapy (attach results); and
- 3. A diagnosis of Lennox-Gastaut syndrome with documentation of an adequate trial and inadequate response with at least two concomitant antiepileptic drugs (AEDs) from the following:
 - a. Valproic acid,
 - b. Lamotrigine,
 - c. Topiramate,
 - d. Felbamate,
 - e. Rufinamide,
 - f. Clobazam, or
- 4. A diagnosis of Dravet syndrome with documentation of an adequate trial and inadequate response with at least two concomitant AEDs from the following:
 - a. Clobazam,
 - b. Valproic acid,

² http://www.iowamedicaidpdl.com/pa_criteria

- c. Levetiracetam,
- d. Topiramate, and
- 5. Is prescribed by or in consultation with a neurologist; and
- 6. The total daily dose does not exceed 20mg/kg/day.

If criteria for coverage are met, initial requests will be approved for 3 months. Additional prior authorization requests will be considered when the following criteria are met:

- 1. Documentation of clinical response to therapy (i.e. reduction in the frequency of seizures); and
- 2. The total daily dose does not exceed 20mg/kg/day.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

3. Changes to Existing Prior Authorization Criteria- Changes are italicized or stricken. See complete PA criteria under the Prior Authorization Criteria tab³.

Benzodiazepines:

Prior authorization is required for non-preferred benzodiazepines. Payment for non-preferred benzodiazepines will be authorized in cases with documentation of previous trial and therapy failure with two preferred products. If a long-acting medication is requested, one of the therapeutic trials must include the immediate release form of the requested benzodiazepine. The prescriber must review the patient's use of controlled substances on the lowa Prescription Monitoring Program website and determine if the use of a benzodiazepine is appropriate for this member.

Requests for clobazam (ONFI) will be considered for a diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 2 years of age and older when used as an adjunctive treatment.

For patients taking concurrent opioids, the prescriber must document the following:

- 1. The risks of using opioids and benzodiazepines concurrently have been discussed with the patient; and
- 2. Documentation as to why concurrent use is medically necessary is provided; and
- 3. A plan to taper the opioid or benzodiazepine is provided, if appropriate.

³ http://www.iowamedicaidpdl.com/pa_criteria

Dupilumab (Dupixent):

Prior authorization is required for Dupixent (dupilumab). Payment will be considered for patients when under the following conditions criteria are met:

- 1. Patient is within the FDA labeled age for indication; and
- 2. Patient has a diagnosis of moderate-to-severe atopic dermatitis; and
 - a. Is prescribed by or in consultation with a dermatologist, *allergist*, *or immunologist*; and
 - g. Dose does not exceed an initial one-time dose of 600mg and maintenance dose of 300mg thereafter given every other week.
- 3. Patient has a diagnosis of moderate to severe asthma with an eosinophilic phenotype (with a pretreatment eosinophil count ≥ 150 cells/mcL within the previous 6 weeks) OR with oral corticosteroid dependent asthma; and
 - a. Is prescribed by or in consultation with an allergist, immunologist, or pulmonologist; and
 - b. Has a pretreatment forced expiratory volume in 1 second (FEV_1) \leq 80% predicted; and
 - c. Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in combination with a controller medication (e.g. long acting beta₂ agonist [LABA], leukotriene receptor antagonist [LTRA], oral theophylline) for a minimum of 3 consecutive months. Patient must be compliant with therapy, based on pharmacy claims; and
 - d. Patient must have one of the following, in addition to the regular maintenance medications defined above:
 - i. Two (2) or more exacerbations in the previous year or
 - ii. Require daily oral corticosteroids for at least 3 days; and
- 4. Dose does not exceed the FDA approved dosing for indication.

Growth Hormone:

Prior authorization (*PA*) is required for therapy with growth hormones. Requests will only be considered for FDA approved dosing. Payment for non-preferred growth hormones will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent. The following FDA approved indications for Growth Hormone therapy are considered not medically necessary and requests will be denied: Idiopathic Short Stature (ISS) and Small for Gestational Age (SGA). Payment will be considered under the following conditions All of the following criteria must be met for approval for prescribing of growth hormones:

Children with Growth Hormone Deficiency

- 1. Standard deviation of 2.0 or more below mean height for chronological age; and-
- 2. No expanding intracranial lesion or tumor diagnosed by MRI; and-
- 3. Growth rate below five centimeters per year; and-

- 4. Failure of any two stimuli tests to raise the serum growth hormone level above ten nanograms per milliliter; and. Stimuli testing will not be required for the following diagnoses: Turners Syndrome, chronic renal failure, and HIV/AIDS.
- 5. Annual bone age testing is required for the diagnosis of Growth Hormone Deficiency. A Bone age 14 to 15 years or less in females and 15 to 16 years or less in males is required; and.
- 6. Epiphyses open.

Pediatric Chronic Kidney Disease

- 1. Is prescribed by or in consultation with a nephrologist; and
- 2. Standard deviation of 2.0 or more below mean height for chronological age; and
- 3. No expanding intracranial lesion or tumor diagnosed by MRI; and
- 4. Growth rate below five centimeters per year; and
- 5. Bone age of 14-15 years or less in females and 15-16 years or less in males; and
- 6. Epiphyses open.

Turner's Syndrome

- 1. Chromosomal abnormality showing Turner's syndrome; and
- 2. Prescribed by or in consultation with an endocrinologist; and
- 3. Standard deviation of 2.0 or more below mean height for chronological age; and
- 4. No expanding intracranial lesion or tumor diagnosed by MRI; and
- 5. Growth rate below five centimeters per year; and
- 6. Bone age of 14-15 years or less in females and 15-16 years or less in males; and
- 7. Epiphyses open.

Prader Willi Syndrome

- 1. Diagnosis is confirmed by appropriate genetic testing (attach results); and
- 2. Prescribed by or in consultation with an endocrinologist; and
- 3. Bone age of 14-15 years or less in females and 15-16 years or less in males; and
- 4. Epiphyses open.

Noonan Syndrome

- Diagnosis is confirmed by the appropriate genetic testing (attach results);
 and
- 2. Prescribed by or in consultation with an endocrinologist; and
- 3. Standard deviation of 2.0 or more below mean height for chronological age; and
- 4. Bone age of 14-15 years or less in females and 15-16 years or less in males; and
- 5. Epiphyses open.

SHOX (Short Stature Homeobox)

- 1. Diagnosis is confirmed by the appropriate genetic testing (attach results); and
- 2. Prescribed by or in consultation with an endocrinologist; and
- 3. Bone age of 14-15 years or less in females and 15-16 years or less in males; and
- 4. Epiphyses open.

Adults with Growth Hormone Deficiency

- 1. Patients who were growth hormone deficient during childhood (childhood onset) and who have a continued deficiency; or
- 2. Patients who have growth hormone deficiency (adult onset) as a result of pituitary or hypothalamic disease (e.g., panhypopituitarism, pituitary adenoma, trauma, cranial irradiation, pituitary surgery); and
- 3. Failure of at least one growth hormone stimulation test as an adult with a peak growth hormone value of ≤5 mcg/L after stimulation.

Adults with AIDS Wasting/Cachexia

- 1. Greater than 10% of baseline weight loss over 12 months that cannot be explained by a concurrent illness other than HIV infection; and
- 2. Patient is currently being treated with antiviral agents; and
- 3. Patient has documentation of a previous trial and therapy failure with an appetite stimulant (i.e. dronabinol or megestrol).

Short Bowel Syndrome

If the request is for **Zorbtive**® [somatropin (rDNA origin) for injection] approval will be granted for the treatment of Short Bowel Syndrome in patients receiving specialized nutritional support. Zorbtive® therapy should be used in conjunction with optimal management of Short Bowel Syndrome. *PA will be considered for a maximum of 4 weeks.*

If the criteria for coverage is met, initial requests Prior authorization will be granted given for 12-months periods per patient as needed, unless otherwise stated above. Additional prior authorizations will be considered upon documentation of clinical response to therapy and patient continues to meet the criteria for the submitted diagnosis.

Lupron Depot- Adult

Prior authorization is required for Lupron Depot (leuprolide acetate). Payment will be considered for patients under the following conditions:

- 1. Patient meets the FDA approved is 18 years of age or older; and
- 3. Patient has a diagnosis of endometriosis for whom which concurrent therapy with a preferred NSAIDs and at least one preferred 3 month course of a continuous course of hormonal contraceptive has failed; or

4. Point of Sale Billing Issues:

a. **ProDUR Quantity Limits:** The following quantity limit edits will be implemented. A comprehensive list of all quantity limit edits appears on the Quantity Limit Chart⁴.

Drug Product	Quantity	Days Supply
Inbrija 42mg	300	30

- b. Morphine Milligram Equivalents (MME): Effective October 1, 2019, the MME per day limit will be reduced from 150 MME per day to 120 MME per day. Prior authorization will be required for use of high-dose opioids ≥ 120 morphine milligram equivalents (MME) per day. Patients undergoing active cancer treatment or end-of-life care will not be subject to prior authorization criteria. The MME edit will continue to be gradually decreased over time to 90 MME per day.
- **5. DUR Update:** The latest issue of the Drug Utilization Review (DUR) Digest is located at the lowa DUR website⁵ under the "Newsletters" link.

We encourage providers to go to the <u>PDL website</u>⁶ to view all recent changes to the PDL. If you have questions, please contact the Pharmacy Prior Authorization Helpdesk at 877-776-1567 or 515-256-4607 (local in Des Moines) or e-mail <u>info@iowamedicaidpdl.com</u>.

6 http://www.iowamedicaidpdl.com/

⁴ http://www.iowamedicaidpdl.com/billing quantity limits

⁵ http://www.iadur.org/